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Gavin J. Milczarek-Desai
Durando Birdwell & Janke PLC
2929 E. Broadway Blvd.
Tucson, AZ 85716

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,611	DAHL, EVA MARIE	
	Examiner	Art Unit	
	Michele C. Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-13 and 16-26* is/are pending in the application.

4a) Of the above claim(s) *16-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed by Applicant on December 23, 2003. Acknowledgment is made of newly submitted Claims 25 and 26.

Election/Restrictions

Newly submitted Claims 25 and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention of Claims 1-5 and 8-13 is drawn to a nutritional supplement comprising vitamin A, vitamin C, vitamin D, a bioflavonoid, and zinc monomethionine, whereas the invention of Claims 25-26 is drawn to a method for supporting a humane immune system against mucosal infection comprising administering a nutritional supplement to a human before or during a mucosal infection, wherein the nutritional supplement includes vitamin A, vitamin C, vitamin D, a bioflavonoid, and zinc monomethionine. Thus, newly submitted Claims 25-26 are drawn to an additional invention, *i.e.,* the use of the composition of the elected invention of Group I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25 and 26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-5 and 8-13 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claims 1-4 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (A) and Hastings (B). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Firstly, the reference of Rowland was relied upon because Rowland teaches a nutritional supplement for administration to humans comprising: 4,167 I.U. of vitamin A (fish liver oil); 200 mg of vitamin C; 167 I.U. of vitamin D (fish liver oil); 20 mg of lemon bioflavonoids; and 3 mg of zinc (gluconate), in Table 4 (*see* Column 11). Rowland teaches that the vitamin composition can be combined with a composition comprising Shilajit or an extract

thereof to be administered to humans to restore energetic balance or intensity, or to enhance a bioenergetic field in a mammal. In Column 5, lines 10-19, Rowland teaches that additional ingredients, *e.g.*, bioflavonoids, herbs, cellulose, and magnesium stearate can be added to enhance the referenced composition. Secondly, the reference of Hastings was relied upon because Hastings teaches a multi-electrolyte composition with nutrients comprising carbohydrates (*i.e.*, fructose and malodextrin); 2-15 mg of zinc monomethionine, and 60 mg of vitamin C for administration to humans, in Column 1, lines 31-67. The composition taught by Hastings provides electrolytes, nutrients and energy lost during physical exertion, or those lacking vital nutrients. The Hastings' composition may further include soybean oil (see Column 3, lines 8-10). Because Rowland does not teach a nutritional supplement comprising zinc monomethionine and because Hastings does not teach a nutritional supplement comprising vitamin A, vitamin D, and a bioflavonoid, the teachings of the aforementioned references were combined because it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the nutritional supplement taught by Rowland with the nutritional supplement taught by Hastings to provide the instantly claimed invention because both Rowland and Hastings teach that the ingredients comprising their nutritional supplements restore energy and provide beneficial health effects when administered to humans.

In response to applicant's argument that neither Roland nor Hastings teaches or suggests the "desirability of combining their nutritional supplement components to arrive at the present invention" because Rowland teaches away from the present invention by

specifying bioflavonoids as a "non-medicinal ingredient" and because the level of unpredictability in the art is such that one of average skill would not have been motivated or had a reasonable chance of success in making the present invention for the purpose of supporting the immune system against mucosal infections (*i.e.*, colds and flus), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Moreover, Applicant's arguments are not commensurate in scope to the limitations of the claimed invention, since nowhere does Applicant claim a composition providing the beneficial functional effect for supporting the immune system against mucosal infection. Furthermore, Applicant does not claim a composition not comprising other additional ingredients, such as the 'Shilajit' comprising the composition taught by Rowland.

Thus, with Rowland and Hastings providing the motivation to combine the instantly claimed ingredients to provide a nutritional supplement that restores energy and provides beneficial health effects when administered to humans, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide a composition for administration to humans, as suggested by the cited references. Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is

based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. Hence, at the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable of success to add the composition taught by Rowland to the composition taught by Hastings because Rowland teaches, in Column 5, lines 31-39, that his composition restores energy balance or enhances a bioenergic field in a mammal and is useful in the treatment of various disease conditions; and Hastings teaches, in Column 2, lines 17-26, that zinc in the form of zinc monomethionine provides better retention and utilization of zinc than other simple zinc compounds and provides a synergistic formula that is important for providing proper immune system function. Therefore, the invention as a whole was clearly *prima facie* obvious in the absence to the contrary.

Claims 1-5 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (A) and Hastings (B) in view of Kharazmi et al. (C). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combined teachings of Rowland and Hastings were relied upon for the reasons set forth immediately above. Because the combined teachings of Rowland and Hastings teach the claimed invention except for 10 mg of rose hips, the secondary reference of Kharazmi was relied upon because Kharazmi teaches a formulation having a rose hip concentrate having a high vitamin content relative to conventionally dried material for administration to humans, in Column 2, lines 33-42. *See* also Table 1 in Column 4. In Column 4, lines 13-16, Kharazmi teaches preferred dosage amounts for the administration of the referenced rose hips composition.

Thus, with the combined teachings of Rowland and Hastings providing the motivation to combine the instantly claimed ingredients in the making of a nutritional supplement for administration to humans, and with Kharazmi providing a composition comprising rose hips with a high vitamin content of vitamin B, E, and C, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide a composition as a nutritional supplement for administration to humans. As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference. Therefore, the invention as a whole was clearly *prima facie* obvious in the absence to the contrary.

Claims 1 and 8-12 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lockett (D) and Hastings (B). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that neither Lockett nor Hastings teach a composition to provide a composition for immune support against mucosal infection, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lockett was relied upon because Lockett teaches a nutritional supplement comprising 8,250-250,000 I.U. of vitamin A, 25-1000 mg of vitamin C, and 100-4000 I.U. of vitamin D, 1.25-50 mg of hesperidin (a lemon bioflavonoid, 5-100 mg of zinc, 8.25-250 mg of rutin (a bioflavonoid), and 8.25-250 mg of citrus bioflavonoid complex. In Column 2, lines 39-52, Lockett teaches that the referenced formulations are useful for a controlled intake of vitamin, mineral and micronutrients that reduce the incidence and severity of sickle cell crises in patients. Hastings was relied upon because Hastings teaches a multi-electrolyte composition with nutrients comprising carbohydrates *(i.e.*, fructose and malodextrin); 2-15 mg of zinc monomethionine, and 60 mg of vitamin C for administration to humans, in Column 1, lines 31-67. The composition taught by Hastings provides electrolytes, nutrients and energy lost during physical exertion, or those lacking vital nutrients. The Hastings' composition may further include soybean oil (see Column 3, lines 8-10). Because Lockett does not teach a nutritional supplement comprising zinc monomethionine and because Hastings does not teach a nutritional supplement comprising vitamin A, vitamin D, and a bioflavonoid, the teachings of the

aforementioned references were combined because it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the nutritional supplement taught by Lockett with the nutritional supplement taught by Hastings to provide the instantly claimed invention because both Lockett and Hastings teach that the ingredients comprising the referenced nutritional supplements provide beneficial functional effects for good health for humans.

Thus, with Lockett teaching a composition comprising vitamins and bioflavonoids that enhances biosynthesis of platelet concentration and increases the production of hemoglobin; and with Hastings providing a composition comprising electrolytes, nutrients and energy lost during physical exertion, or those lacking vital nutrients, and, teaching that zinc in the form of zinc monomethionine provides better retention and utilization of zinc than other simple zinc compounds and provides a synergistic formula that is important for providing proper immune system function, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide a composition for administration to humans, as suggested by the cited references. Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference. Therefore, the invention as a whole was clearly *prima facie* obvious in the absence to the contrary.

Claims 1 and 8-15 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lockett (D) and Hastings (B) in view of in view of Kharazmi et al. (C). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combined teachings of Locket and Hastings were relied upon for the reasons set forth above. Because the combined teachings of Lockett and Hastings teach the claimed invention except for wherein the nutritional supplement further contains additional amount of about 10 mg of rose hips, the secondary reference of Kharazmi was relied because Kharazmi teaches a formulation having a rose hip concentrate having a high vitamin content relative to conventionally dried material for administration to humans, in Column 2, lines 33-42. See also Table 1 in Column 4. In Column 4, lines 13-16, Kharazmi teaches preferred dosage amounts for the administration of the referenced rose hips composition.

Thus, contrary to Applicant's arguments, at the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the rose hips taught by Kharazmi to the nutritional supplement taught by the combined teachings of Lockett and Hastings to provide the claimed invention because Kharazmi teaches a rose hip concentrate comprising a high content of vitamin B, E, an C, with about 560 mg of vitamin C per 100 g powder (*see* Column 3, lines 32-34) and having beneficial health effects.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been

routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele C. Flood whose telephone number is (571) 272-0964. The examiner can normally be reached on 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCF
March 10, 2004

CHRISTOPHER R. TATE
PRIMARY EXAMINER